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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,547	07/29/2003	Mark T. Marshall	P0011313.01	7482

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
10/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,547	MARSHALL ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 7-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Terminal Disclaimer filed 20 June 2008.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 20 June 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 7,191,016 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

2. Applicant's arguments filed 20 June 2008 have been fully considered but they are not persuasive.

3. Regarding Carson'862, Applicant argues that Carson'862 fails to teach a porous silicone layer or a sheet of collagen fibers formed over the second electrode. Applicant cites as evidence that Cason only mentions collagen as a gelatin-type pore impregnating material in a wetting process, and that gelatin is an irreversibly hydrolyzed form of collagen where strands separate into globular, random coils. It is noted that Carson'862 always presents gelatin and collagen in the alternative (a sheet comprising gelatin OR collagen), such that it is not inherent or disclosed that collagen must be a gelatin, or that the collagen is hydrolyzed. As such, it is contemplated that Carson'862 is disclosing collagen in its natural fibrous state. Alternatively, even if Carson'862 were disclosing gelatinous collagen, the random coils still constitute fibers, such that a layer comprising the coils would comprise collagen fibers.

4. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Houser'559 teaches that a coating of collagen will decrease thrombosis and increase bonding of the coating to the device itself as cited. Houser'559 also explicitly uses the language of "sheet" in the cited portions in reference to a sheet of collagen covering the electrode. It is further noted that Houser'559 teaches that a coagulum rather than tissue itself enters the collagen structure to form a bond with the tissue, such that Houser'559 does not teach tissue ingrowth or thereby teach away from or confound the Carson'862 device or the Krall'909. Therein, Houser'559 provides motivation for combination of collagen as a beneficial coating material beyond the intended use of tissue ingrowth or other means of binding the device to tissue.

5. In response to applicant's argument that the references fail to teach preventing anodal stimulation, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is seen that

Carson'862 shows a bipolar configuration with two electrodes 10 and 20. Similarly, Krall'909 shows two electrodes 8 and 10.

6.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 7-10, 16-18, 20-29 and 35-47 stand rejected under 35 U.S.C. 102(b) as anticipated by Carson (US Patent Number 5,931,862, hereinafter Carson'862) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carson'862 in view of Houser et al. (US 6,361,559, hereinafter Houser'559).

Regarding claims 1-2, 20, 21, 43, 44 and 47, Carson'862 shows a medical electrical lead (Fig. 1, lead 12) comprising an elongated body with a first elongated insulated conductor, a second elongated insulated conductor (column 4, lines 52-63) and a connector with a first and second electrical contact formed at a proximal end (connectors 22 and 24); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Figs. 2 & 3, distal pacing electrode 20, helical coil or tined formations); a second low voltage electrode joined to the lead body in proximity to the first electrode (underlying electrode 16); and a porous layer formed over the second electrode (porous tubular covering 10); wherein the outer surface of the second

electrode (16) is recessed from the outer surface of the lead body (Fig. 2) and the outer surface of the porous layer (10) is isodiametric with the outer surface of the lead body (column 2, lines 39-44).

Further regarding claim 1, Carson'862 discloses that the layer 10 covering the electrodes may be impregnated with collagen via perfusion, which is taken to reasonably disclose a sheet of collagen fibers, since the ePTFE sheet will be evenly distributed with the perfused collagen fibers (column 8, lines 50-65). Alternatively, in the same field of endeavor, Houser'559 teaches covering electrodes with a porous material, such as collagen, to further define a structure for tissue to shrink and coagulate, to encourage neointimal cell growth, and to enhance thermal bonding between the device structure and vessel wall (column 23, line 60 through column 24, line 25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Carson'862 with the collagen layer covering the electrode structures as taught by Houser'559 to provide Carson'862 with the same advantages.

Further regarding claims 20 and 21, Carson '682 discloses that the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48). The prevention of chronic tissue ingrowth, which prevents the electrode from coming in direct contact with the tissue, is a sufficient and effective means of preventing the electrode from stimulating tissue in proximity to the electrode. Alternatively, the pulse generator (Fig. 1, generator 11) of Carson'862 must inherently contain a control means used in the art, such as a microprocessor. That control means provides a means for preventing the second electrode from stimulating the tissue as the alternate state to control-driven

stimulation of tissue. If the device is off, or the second electrode channel is powered down or in a blanked state, the control means is preventing the second electrode from delivering stimulation to the tissue.

Regarding claims 7-10 and 26-29, Carson'862 discloses a means to promote wetting comprising a wetting agent which can be a surfactant and a surface treatment of the porous layer (column 2, line 54 through column 3, line 26).

Regarding claims 16 and 35, Carson'682 discloses the invention as previously recited wherein the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48).

It is noted that the component of a second elongated lead body in the instant application does not distinguish over the device of Carson'682 because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment of the Carson'682 system, where connector branches 22 and 24 with porous coverings 10' and 10'' could extend for the full length of the device and in such a configuration constitute a first and second lead body, each containing one of the pacing/sensing electrodes and capable of being implanted in the cardiac vein or the right ventricle (as shown in Figure 1).

Regarding claims 22-25, Carson'862 discloses that the porous layer may comprise silicone, polyurethane, expanded PTFE, or collagen (column 2, lines 39-53; column 5, lines 10-23).

Regarding claim 36, bipolar or near-field sensing are well known in the cardiac pacing art, and therefore do not distinguish over the combination of Carson'862 in view

of Houser'559. Additionally, Houser'559 teaches bipolar sensing (column 15, line 65 through column 16, line 16).

Regarding claims 37-39, Carson'862 discloses the invention substantially as claimed including spaced electrode pairs, but does not expressly disclose the range between 2-9 mm. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a spacing of 2-9mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

Regarding claims 40 and 42, any of electrodes 16 and 20 (Fig. 2); 20, 38, 42, and 44 (Fig. 3) are capable of functioning as the anode or cathode such that the cathode electrode assembly could be positioned distal to the anode electrode assembly, or such that the anode could be positioned distal to the cathode.

Regarding claim 41, Carson'862 shows a fixation helix (Fig. 1, helix 20).

Further regarding claim 44, and regarding claims 17, 18, 45 and 46, Carson'862 shows the lead body placed in a cardiac vein, passing through an atrium, and within the right ventricular chamber (Figs. 1 and 2).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 11-14, 30-33 and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 or Carson'862 in view of Houser'559 as applied to claim 1 above, and further in view of Hull et al. (US Patent 5,269,810, hereinafter Hull'810).

Carson'862 shows the invention substantially as claimed, but does not disclose the thickness of the porous layer (2-9 mm) or the desired size range for the pores in that layer (0.4-50 microns).

In the same problem solving area, Hull'810 teaches an electrode-covering layer that is about 0.13 mm (0.005 inches) thick with fibril length (i.e. internodal distance and pore size) of 10 microns for the advantages of being highly biocompatible, highly flexible, and long-lasting (column 3, lines 32-45; column 4, lines 1-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar structural criteria with the Carson'862 invention for the same advantages of biocompatibility, flexibility and long lifespan (motivation to combine provided by Hull et al., column 3, lines 32-45; column 4, lines 1-15).

11. Claims 12-15, 31-34 and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 or Carson'862 in view of Hauser'559 as applied to claim 1 above, and further in view of Soukup et al. (US Patent 5,466,252).

Carson'862 shows the invention substantially as claimed, but does not disclose the desired size range for the pores in that layer (0.4-50 microns).

In the same field of endeavor, Soukup et al. teaches an implantable lead with a porous PTFE layer with preferred fibril lengths greater than 4 microns, and most preferably greater than 10 microns to provide the necessary amount of flexibility and extensibility for the intended application and to present an acceptable biocompatible surface to the blood chemistry to which the outer surface of the lead will be exposed (column 2, lines 26-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar parameters for the lead body covering in the Carson'862 invention to provide the same advantages of flexibility and biocompatibility (motivation to combine provided by Soukup et al., column 2, lines 26-34).

12. Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 or Carson'862 in view of Houser'559 as applied to claim 1 above, and further in view of Kroll (US Patent 6,327,498).

Carson'862 shows the invention substantially as claimed, but does not disclose a third high voltage electrode adapted for defibrillation stimulation.

In the same field of endeavor, Kroll'498 teaches a third electrode (Fig. 2, electrode 46) placed proximal to a second electrode (32) and distal to a first electrode (34) for the purpose of providing shocking stimulation pulses (column 7, lines 64-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a third electrode in the Carson'862 device for the same advantage of applying shocking stimulation (defibrillation) to the heart (motivation to combine provided by Kroll'498 column 7, lines 64-67).

13. Claims 1, 2, 7-10, 11, 16, 20-30 and 35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al. (WO 02/089909 A1) in view of Houser'559.

Regarding claims 1-2, 20 and 21, Krall et al. shows a medical electrical lead (Fig. 1, lead body 6) comprising an elongated body with a first elongated insulated conductor, a second elongated insulated conductor (Fig. 2 coiled electrical conductor 14, second electrical conductor 16) and a connector with a first and second electrical contact formed at a proximal end (connectors 4); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Fig. 2, distal tip electrode 10); a second low voltage electrode joined to the lead body in proximity to the first electrode (coiled electrode portion 8, coiled electrode 24); and a porous layer formed over the second electrode (porous thin film 30); wherein the outer surface of the second electrode (24) is recessed from the outer surface of the lead body (Fig. 2) and the outer surface of the porous layer (30) is isodiametric with the outer surface of the lead body (column 2, lines 39-44).

Further regarding claim 1, Krall et al. discloses the invention substantially as claimed, but does not expressly disclose that the layer covering the electrode comprises silicone or a sheet of collagen fibers. In the same field of endeavor, Houser'559 teaches covering electrodes with a porous material, such as collagen, to further define a structure for tissue to shrink and coagulate, to encourage neointimal cell growth, and to enhance thermal bonding between the device structure and vessel wall (column 23, line 60 through column 24, line 25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Krall et al.

with the collagen layer covering the electrode structures as taught by Houser'559 to provide Carson'862 with the same advantages.

Regarding claims 7-10,11, 16, 22-30 and 35, Krall et al. discloses that the cover comprises a porous polymer (claim 1), preferably ePTFE (claim 8); is relatively thin, on the order of .13mm (or .005inches) thick (page 3, lines 5-6; page 10, lines 26 through page 11, line 4); is adapted to prevent chronic tissue ingrowth (page 3, lines 10-13); and comprises a means of wetting (claims 13-14, surfactant polyvinyl alcohol).

It is noted that the component of a second elongated lead body in the instant application does not distinguish over the device of Krall et al. because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment of the Krall et al. system, where connectors (4) could extend for the full length of lead assembly (2) and in such a configuration constitute a first and second lead body, each containing one of the pacing/sensing electrodes and capable of being implanted in the cardiac vein or the right ventricle (as shown in Figure 1).

14. Claims 1, 2, 16-24 and 35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Belden (US Patent 6,847,845, hereinafter Belden'845) in view of Houser'559.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1, 2, 16-24 and 35, Belden'845 discloses a medical system comprising an implantable medical device (80); a first elongated lead body (10) implanted in a cardiac vein with a first electrode (12) adapted for intimate contact with tissue and a second electrode (16) with a porous layer (32) formed over the second electrode which may be isodiametric and comprised of ePTFE, silicone, or polyurethane (column 3, lines 20-25, 47-56) and adapted to prevent chronic tissue ingrowth (column 3, line 64 through column 4, line 5); a second elongated lead body (70) implanted in the right ventricle (column 5, lines 54-67) with a second electrode (72); and comprising a third high voltage electrode adapted for defibrillation stimulation (defibrillation coil 74).

Further regarding claim 1, Belden'845 discloses the invention substantially as claimed, but does not expressly disclose that the layer covering the electrode comprises silicone or a sheet of collagen fibers. In the same field of endeavor, Houser'559 teaches covering electrodes with a porous material, such as collagen, to further define a structure for tissue to shrink and coagulate, to encourage neointimal cell growth, and to enhance thermal bonding between the device structure and vessel wall (column 23, line 60 through column 24, line 25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Belden'845 with the collagen layer covering the electrode structures as taught by Houser'559 to provide Carson'862 with the same advantages.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

21 October 2008

/George Manuel/
Primary Examiner